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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,387	12/07/2000	Gregory Donoho	LEX-0104-USA	7426

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/28/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/733,387

Applicant(s)

DONOHO ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicants' election without traverse of Group I (Claims 1-3), drawn to an isolated nucleic acid molecule of SEQ ID NO: 43 or encoding the amino acid sequence set forth in SEQ ID NO: 44, in Paper No. 8 is acknowledged.
2. Applicants' claim amendment of 6/4/2002 in Paper No. 8 is acknowledged. Claims 4 and 5 have been canceled. Claims 1 and 2 have been amended. Claims 1-3 are pending and under consideration.

### ***Priority***

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application, 60/169,427, filed on 12/07/1999.

### ***Rejections—35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-3 are drawn to the nucleic acid molecule of SEQ ID NO: 43 that encodes a human protein that shares sequence similarity with mammalian

membrane proteins, G-protein coupled receptors (GPCRs). The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

The instant disclosure asserts that the deduced amino acid sequence set forth in SEQ ID NO: 44 encoded by the claimed nucleic acid has structural motifs found in the 7 transmembrane receptor family (page 2, line 11-13). Nonetheless, the disclosure fails to disclose the degree of homology and fails to provide any information or evidence on the biological functions or activities of the claimed molecules. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? *Nature Genetics* 18:313-318,1998). There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al. G-protein-coupled receptors, *J. Biol. Chem.*, 273:17299-17302, 1998). In certain cases, a change of two-amino acid residues in a protein results in switching the binding of the protein from one receptor to another (Yan et al, *Science*, 290:523-527, 2000). Thus, all the asserted utilities in the disclosure based upon the protein homology are not specific and substantial, as exemplified below.

The instant disclosure asserts that the nucleotide sequences can be used to regulate gene expression (page 2, 2<sup>nd</sup> paragraph; page 5, 3<sup>rd</sup> paragraph; page 9, 2<sup>nd</sup> paragraph). The disclosure also asserts utilities of the claimed nucleic acid molecules as hybridization probes for screening libraries (page 11, 1<sup>st</sup> paragraph). The disclosure further asserts the use of the claimed protein in generation of antibodies (page 15, line 1). However, such uses are all considered research uses only designed to identify a particular function of the claimed molecules and are not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility." Moreover, such uses are not specific to the instant molecule but applicable to any nucleic acid molecules or proteins.

The instant disclosure further asserts that the claimed nucleic acid molecules can be used to identify mutations associated with a particular disease or in diagnostic/prognostic assays (page 5, last paragraph). The disclosure additionally asserts that the claimed nucleic acid molecules, proteins, fusion proteins, and antibodies "can be useful" for the treatment of diseases, or for screening agonists, antagonist, and drugs (page 3, last paragraph; page 4, last paragraph-page 5, 1<sup>st</sup> paragraph). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The specification fails to disclose the biological functions of the claimed molecules and any diseases that are associated with or can be treated with the claimed molecules. Clearly, further research would be required to identify a disease that is associated with the claimed

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molecules or a disease that can be treated with the claimed molecules. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The assertion that the human protein encoded by the claimed nucleic acid molecules has the sequence similarity with mammalian membrane proteins or GPCRs does not endow the claimed molecules with a specific and substantial utility. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

6. Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the nucleic acid molecule of SEQ ID NO: 43 or encoding the amino acid sequence set forth in SEQ ID NO: 44 were to have a patentable utility, the instant disclosure would not be found to be enabling for the full scope of the claimed invention comprising a genus of at least 22 contiguous nucleotides of SEQ ID NO: 43.

The factors that are considered when determining whether a disclosure

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satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 recites a genus of nucleic acid molecules of any size that has at least 22 contiguous nucleotides of SEQ ID NO: 43. However, other than the nucleic acid molecule of SEQ ID NO: 43 or encoding the amino acid sequence set forth in SEQ ID NO: 44, the disclosure has not provided sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claim. The disclosure has not shown (i) which portions of SEQ ID NO: 43 are critical to the activity of the protein of SEQ ID NO: 44; and (ii) what modifications (e.g., substitutions, deletions or additions) one can make to SEQ ID NO: 43 will result in protein mutants with the same functions as the protein of SEQ ID NO: 44. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Accordingly, the disclosure fails to enable such a myriad of the claimed nucleic acid molecules that not only vary substantially in length but also in nucleotide composition and to provide any guidance to those skilled generally on how to make and use the claimed genus of nucleic acid molecules. Thus, it would require undue experimentation for one skilled in the art to make and use the claimed genus of nucleic acid molecules embraced by the instant claim.

***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification discloses a nucleotide sequence set forth in SEQ ID NO: 43 or encoding the amino acid sequence set forth in SEQ ID NO: 44. However, Claim 1 recites a genus of nucleic acid molecules comprising at least 22 contiguous nucleotides of SEQ ID NO: 43. Thus, it encompasses virtually any random sequence of any length as long as it has a stretch of at least 22 consecutive nucleotides that is the same as SEQ ID NO: 43.

The instant disclosure of a single species of nucleic acid of SEQ ID NO: 43



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does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the claimed genus of nucleic acid molecules. There is no description of the conserved regions that are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed nucleic acid molecules as being identical to those instantly claimed.

Due to the breadth of the claim genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday—Friday, 8:30 am—5:00 pm.

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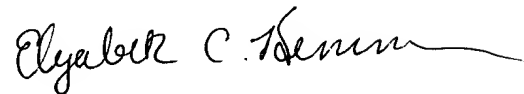
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
June 21, 2002



ELIZABETH KEMMERER  
PRIMARY EXAMINER